REMARKS

The objections to the specification and claims will be addressed upon acknowledgment that the claims are otherwise directed to allowable subject matter.

Traversal of the Examiner's Rejection of Claim 20
As Being Indefinite Under Section 112, Second Paragraph

The Examiner rejected Claim 20 as being indefinite under Section 112, Second Paragraph because the specification failed to define the phrase "resisting a digestive enzyme" as well as "digestive enzyme."

Pepsin, trypsin and chymotrypsin, which are digestive enzymes of the alimentary tract, are identified at page 1 of the specification as serine protease inhibitors. It is clear from the present specification that "resisting a digestive enzyme" refers to inhibiting serine proteases of the alimentary tract. Reconsideration by the Examiner and withdrawal of this rejection is respectfully requested.

Traversal of the Examiner's Rejection of Claims 14, 15, 17,
18 and 20 For Non-Enablement Under Section 112, First Paragraph

Claims 14, 15, 17, 18 and 20 were rejected because the specification, in the Examiner's opinion, did not reasonably provide enablement for treating disseminated vascular coagulation or inhibiting digestive enzymes using any anhydridized serine protease that is capable of inhibiting the reaction of any serine protease by competitively binding the substrate of any serine protease.

The Examiner acknowledges that the specification is enabling for treating disseminated vascular coagulation with four anhydridized serine proteases. MPEP Section 2164.02 teaches that the claims are enabled if one can extrapolate from this that the entire scope of the claims are enabled from this, and the burden is on the Examiner to state why this would not be the case.

Section 2164.02 teaches that applicants do not have to disclose all functioning anhydridized serine proteases, or all residues appropriate for anhydridization, or all regions that can be modified without affecting activity, or the full extent the protease inhibitors tolerate modification, or a scheme for modifying any residue to obtain the desired biological function, or how to select successful candidates from all possible choices. All that is required is that what is disclosed bears a reasonable correlation to the scope of the claim.

Here, the claims are limited to those anhydridized serine proteases capable of inhibiting a serine protease by competitive binding. This excludes those which do not obtain the desired activity. Because the Examiner acknowledges that four species are enabled, and clearly many more can be extrapolated from this information, an enabling disclosure has been provided that reasonably correlates to the scope of the claims.

Regarding Claim 20, guidance for identifying patients in need of treatment by a method for resisting a digestive enzyme is found at the bottom of page 19. Serine protease inhibitors are identified that are effective for treating abdominalgia and hyperamylasemia by inhibiting activation of trypsinogen.

Reconsideration by the Examiner and withdrawal of the enablement rejection is therefore respectfully requested.

Traversal of the Examiner's Rejection of Claims 14, 15, 17, 18 and 20
Under the Written Description Requirement of Section 112, First Paragraph

The Examiner rejected Claims 14, 15, 17, 18 and 20 under the written description requirement of Section 112, first paragraph, because, according to the Examiner, the descriptive portion of the application does not reasonably convey applicants' possession of the claimed invention at the time the application was filed.

Four actual successful reductions to practice of the invention are shown. One skilled in the art would recognize from this that applicants' were fully in possession of

methods using anhydridized serine proteases capable of inhibiting a serine protease by competitive binding.

Regarding Claim 20, as noted above, guidance for identifying patients in need of treatment by a method for resisting a digestive enzyme is found at the bottom of page 19 and serine protease inhibitors are identified that are effective for treating abdominalgia and hyperamylasemia by inhibiting activation of trypsinogen. From the anhydridization techniques disclosed in the Examples, one skilled in the art would recognize that applicants' were fully in possession of the subject matter of claim 20.

Given the strong presumption that an adequate written description is present when an application is filed, reconsideration by the Examiner and withdrawal of this rejection is respectfully requested.

Traversal of Examiner's Section 102(b) Rejection of
Claims 14 - 18 as Being Anticipated by Wolf et al. or Berkner et al.

The Examiner cites Wolf et al. and Berkner et al. as disclosing the treatment of disseminated intravascular coagulation using a variant of Factor X in which the active-site serine residue is converted to an alanine residue. As depicted in the formula at the bottom of page 9, anhydridized serine residues are formed by converting the $-CH_2$-OH groups of serine residues to $=CH_2$ groups. This is a dehydoalanine residue, not an alanine residue. The cited prior art therefore fails to anticipate Claims 14 – 18, and reconsideration by the Examiner and withdrawal of this rejection is respectfully requested.

Traversal of Examiner's Section 103(a) Rejection of
Claims 14 – 18 as Being Obvious in View of Wolf et al. or
Berkner et al. in view of Ashton et al. and further in view of Levi et al.

The relative positions of the Examiner and applicants regarding Wolf et al. and Berkner et al. are discussed above. Ashton, et al. is cited as teaching that blood coagulation factors in which the original, active site serine is converted to dehydroalanine are enzymatically inactive just like blood coagulation factors in

which the active site serine is converted to alanine. However, neither Ashton, et al. nor Wolf, et al. or Berkner, et al. teach that enzymatically inactive blood coagulation factors can be used to treat disseminated intravascular coagulation.

The Examiner cites Levi et al. as providing the motivation for doing this. However, Levi et al. is not prior art to the present application, which has a 1999 priority date. Therefore, none of the prior art cited by the Examiner leads one of ordinary skill in the art to use blood coagulation factors with active-site serine residues converted to dehydroalanine to treat disseminated intravascular coagulation. Reconsideration by the Examiner and withdrawal of this rejection is therefore respectfully requested.

Conclusion

For the reasons expressed above, applicants request respectfully that the Examiner reconsider and withdraw the rejections under §§102 and 112.

In view of the foregoing amendment and remarks, an early and favorable action is requested respectfully.

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Respectfully submitted,

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